

## **NHGRI IRB: Checklist for Continuing Reviews** *(Include 1 copy with submission)*

Principal Investigator: \_\_\_\_\_

Protocol Number: \_\_\_\_\_ Title: \_\_\_\_\_

### **I. CONTINUING REVIEWS ANNUALLY (*original + 25 stapled copies*)**

- ☐ Form 1195-1 signed by PI, Accountable Investigator, Branch Chief
- ☐ Cover memo addressing:
  - a) A concise statement regarding protocol progress to date and key findings, any departures/withdrawals, adverse events, protocol violations, or other protocol variations.
  - b) Address any "Yes" responses to questions on 1195-1 (i.e., slower than expected accrual, complications/side effects, withdrawals, etc).
  - c) Whether there will be continuing accrual of research participants.
  - d) Reason(s) for continuing the study.
  - e) Any amendments made within the last year.
  - f) Currently proposed changes in protocol or consent form.
  - g) Any changes in the protocol that would require a new consent form to be signed.
  - h) Any study publications (if none, please state "NONE").
- ☐ Amended pages, with the additions and ~~deletions~~, so noted.
- ☐ Table of contents listing protocol and any appendices, recruitment materials, and consent forms.
- ☐ Revised version of protocol, including Ongoing Research Participant Enrollment Report.
- ☐ Up-to-date consent form.
- ☐ A copy of IRB stipulations/recommendations from previous year.

### **II. RESPONSES TO STIPULATIONS FOR CONDITIONALLY APPROVED PROTOCOLS**

- ***original + 25 stapled copies if full IRB review required***
- ***original + 6 stapled copies if IRB Subcommittee review required***
- ***original + 3 stapled copies if NHGRI IRB Chair review required***
- ☐ Cover memo responding point-by-point to stipulations.
- ☐ Revised pages of protocol and consent, with the additions and ~~deletions~~, so noted.
- ☐ Copy of IRB Meeting Minute Stipulations.
- ☐ Clean copies of entire revised protocol and consent.
- ☐ Diskette or e-mail containing clean, final copy of consent form.

Materials for full IRB review must be submitted to Peggy McKoy Bldg 49, Room 4A14 by Noon on the due date, or they may be reviewed at a later meeting. (See NHGRI IRB Calendar).

***For questions regarding the checklist or submissions, please contact:***

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